IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE THE APPLICATION OF AMGEN INC.	)	Misc. Case. No. _____

DECLARATION OF DR. DOMINIK GÖBEL
IN SUPPORT OF APPLICATION PURSUANT TO 28 U.S.C. § 1782

I, Dominik Göbel, declare and state under penalty of perjury pursuant to 28 U.S.C. § 1746 as follows:

1. I am a partner at Gassauer-Fleissner Attorneys at Law in Austria. I am licensed to practice law in Austria and have 15 years of experience in civil and commercial litigation, in particular patent infringement cases, before various Austrian courts, including the Commercial Court Vienna. Our law firm has been retained by Amgen Inc. ("Applicant" or "Amgen") to assist with an anticipated preliminary injunction proceeding against Sandoz GmbH, Biochemiestraße 10, 6250 Kundl, Tirol, Austria, registered under FN 50587v in the Commercial Register at the Regional Court Innsbruck ("Sandoz GmbH"), in Austria before the Commercial Court Vienna.

2. I make this declaration in support of Amgen's *ex parte* application for an order under 28 U.S.C. § 1782 permitting discovery from Sandoz, Inc. for use in an anticipated preliminary injunction proceeding to enjoin manufacture of Sandoz's denosumab biosimilar (GP-2411) in Austria.

3. I am familiar with the information set forth in this declaration based on (a) my personal knowledge; (b) my, or my team's, review of relevant documents; and

(c) information and instructions supplied to me by Applicant or by professionals retained by it. Nothing in this declaration, or in any other document related to these proceedings, discloses privileged communications involving my client, Amgen, nor is anything in this declaration intended to waive any applicable privilege, including the attorney-client privilege and attorney work product privilege. The facts and matters testified to herein are true to the best of my knowledge and belief. I am over the age of 18, and if called as a witness, I could, and would, competently testify thereto.

I. AMGEN BACKGROUND

4. Amgen is known as a biopharmaceutical company that is dedicated to serving patients by developing innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

5. To that end, Amgen has made significant investments in research and development, and two of Amgen drug products, Prolia® and XGEVA®, are the fruits of that labor. These products both contain the active ingredient denosumab. Prolia is generally indicated for the treatment of osteoporosis, and XGEVA is generally indicated to treat bone cancers.

6. Amgen maintains an extensive patent portfolio that covers denosumab and methods of manufacturing biologic drugs, including the European patents (and their Austrian equivalents) discussed below.

II. SANDOZ BACKGROUND & PRODUCTION OF DENOSUMAB BIOSIMILAR IN AUSTRIA

7. The Sandoz group is the generic and biosimilar drugs division of the Novartis group.[1] Sandoz GmbH is the Austrian branch of the Sandoz group. At its facilities in

[1] Novartis has announced plans to spin off Sandoz into a separate company in 2023.

Kundl and Schaftenau (a part of Langkampfen), two municipalities in the Austrian province Tyrol, Sandoz GmbH operates major development and production sites for biotechnologically manufactured medicinal products, biopharmaceuticals and biosimilars (pages 9, 12, Exhibit 1, Sustainability Report 2022 for Novartis Austria). In 2021, the company had 4718 employees and a revenue of € 1,9 billion (Exhibit 2, information about Sandoz GmbH taken from Austrian company information database "WIRTSCHAFTS-COMPASS").[2]

8. At the date of the signing of this declaration, both Sandoz GmbH and Sandoz Inc. are branches of the Sandoz Group.

9. Sandoz GmbH announced in a letter to Amgen dated March 24, 2023 (see Exhibit 3) that it will manufacture a denosumab biosimilar in Austria. Sandoz GmbH provided this information to claim the exemption of the SPC manufacturing waiver, which generally provides that the manufacture of a medicinal product within Europe would not infringe a Supplementary Protection Certificate if certain provisions of the applicable European regulation are met. Specifically, Sandoz GmbH announced that it will make, in Austria, a medicinal product containing denosumab, for the purpose of:

1) export to countries outside of the European Union, and

2) storing of such a product for the purpose of placing it on the market of Member States of the European Union after the expiry of Amgen's Supplementary Protection Certificate ("SPC") SZ 44/2010.

10. Sandoz GmbH's letter also explained that manufacturing of the denosumab biosimilar for export outside of the European Union could begin as early as three months from the

[2] For the Court's convenience, I have included machine translations of any foreign language documents attached as exhibits.

date of the notification. Therefore, there is an imminent threat that Sandoz GmbH will start manufacturing its denosumab biosimilar in Austria.

III. ANTICIPATED AUSTRIAN PRELIMINARY INJUNCTION PROCEEDING

11. Without prejudice to claims based on the Supplementary Protection Certificate SZ 44/2010, Amgen is investigating whether the manufacturing process for Sandoz's anticipated denosumab biosimilar infringes any of Amgen's patents. If applicable at all, the SPC manufacturing waiver could only provide for a defense against the infringement of the SPC SZ 44/2010 and would not be relevant with regard to any other IP rights. Amgen is prepared to file preliminary injunction and main proceedings against Sandoz GmbH once sufficient evidence of imminent or actual infringement is identified. Among other rights, Amgen is prepared to enforce *at least* the following process patents, which are validated and in force in Austria:

- EP 1 984 517 B1, Austrian Reg. No E 573 136, "*Methods for modulating mannose content of recombinant proteins*", expiration date January 23, 2027, which is the counterpart to U.S. Patent No. 9,359,435;
- EP 2 601 287 B1, Austrian Reg. No 705 746, "*Dipeptides to enhance yield and viability from cell cultures*", expiration date August 5, 2031, which is the counterpart to U.S. Patent Nos. 11,130,980 and 11,299,760; and
- EP 2 173 861 B2, Austrian Reg. No E 506 432, "*Methods of treating cell culture media for use in a bioreactor*", expiration date June 12, 2028, which is the counterpart to U.S. Pat. No. 9,320,816.

(hereinafter together the "Patents")

12. As listed above, each of the Patents have a corresponding patent that was issued in the United States. These U.S. patents are listed among other Amgen patents on the U.S.

Food and Drug Administration's Purple Book Patent List, which is publicly available at https://purplebooksearch.fda.gov/patent-list. I understand that the Purple Book Patent List identifies patents for which Amgen believes a claim of patent infringement could reasonably be asserted against Sandoz if it engaged in the making, using, offering to sell, selling or importing of its proposed denosumab biosimilar product in the United States.

13. Patent infringements may be enforced in Austria both through preliminary injunction and main proceedings before the Commercial Court Vienna (Section 162 *Patentgesetz*, Austrian Patent Act, hereinafter "PatG"). Preliminary injunctions are available if the plaintiff evidences the infringement and the validity of the enforced patent (Section 151b PatG). Evidence for infringement must either show a past or ongoing infringement act or that there is an imminent threat of future infringement (Section 147 PatG). Thus, even mere preparatory acts can justify a claim for injunctive relief if, based on certain facts, the concrete concern of an imminent infringement is justified (*Oberster Gerichtshof*, Austrian Supreme Court, hereinafter "OGH", 31.05.1988, 4 Ob 28/88). It is not required to demonstrate any irrevocable harm (Section 151b para 3 PatG, Section 381 *Exekutionsordnung*, Austrian Enforcement Code). When deciding on the grant of a preliminary injunction, the court does not conduct a balance of interest either. However, the defendant's interests may be protected by a security deposit (OGH 19.11.2009, 17 Ob 24/09t). The required standard of proof in preliminary injunction proceedings is the predominant likelihood of a fact, which is lower than in main proceedings where proof beyond reasonable doubt is required (Section 274 *Zivilprozessordnung*, Civil Procedural Code, hereinafter "ZPO"; OGH 28.05.2015, 9 ObA 42/15i). Generally, the plaintiff bears the burden of proof for all necessary elements of its claim. However, the grant of a patent serves as *prima facie* evidence for its validity (OGH 20.12.2018, 4 Ob 228/18k). The defendant can rebut this presumption of validity by submitting

evidence and arguments showing the invalidity of the enforced patent (OGH 23.09.2008, 17 Ob 26/08k). Regarding infringement, the plaintiff bears the burden of proof. Preliminary injunction proceedings are front loaded. All necessary evidence must be submitted together with the preliminary injunction request since there is no procedural guarantee for a second round of briefs. Furthermore, the court may reject a preliminary injunction request if the initial brief is not sufficiently supported by evidence. All means of evidence can be submitted in preliminary injunction proceedings as long as they are readily available (Section 274 ZPO). Readily available means of evidence are, e.g., documents which can be immediately submitted to the court even if they are in a foreign language (OGH 09.08.2006, 4 Ob 138/06g), witness deposition testimony, or witnesses that can be summoned without causing an undue delay (OGH 17.12.1991, 4 Ob 126/91).

14. In addition to arguments against validity and infringement, other defenses, such as the so-called "Bolar exemption", which allows the use of a patented invention for the purpose of obtaining regulatory approval, could be raised as a defense in preliminary injunction proceedings. However, under Austrian law, the Bolar exemption is strictly limited to acts necessary for studies and trials required for obtaining a marketing authorization (Section 22 para 1 PatG). Thus, any manufacturing going beyond this purpose, in particular production for sale, including export or stockpiling for such purposes, would be an infringement. Therefore, the Bolar defense would most likely not be successful in the present case. As already mentioned above, neither would the SPC manufacturing waiver be available as a defense against the enforcement of the Patents. This exception applies to export and stockpiling under certain circumstances but only applies to Supplementary Protection Certificates (Article 5 para 2 Regulation (EC) No 469/2009 as amended by Regulation (EU) 2019/933) and thus by definition does not apply to the Patents,

which are still within their natural patent term. Austrian preliminary injunction proceedings would therefore focus on validity and infringement.

15. Important for a preliminary injunction to be filed against Sandoz GmbH based on one or more of the Patents is thus evidence showing the predominant likelihood that Sandoz GmbH infringes the Patents or that there is an imminent threat of such infringement, i.e., that Sandoz GmbH uses or threatens to use the protected processes and methods in Austria. In case Sandoz GmbH attacks the validity of the Patents in preliminary injunction proceedings, also counterarguments and evidence showing the validity of the Patents would be necessary. Other evidence or preparatory steps (such as warning letters) are not required for a preliminary injunction under Austrian law.

IV. AUSTRIAN RULES PERTAINING TO DISCOVERY AND DISCLOSURE OF EVIDENCE

16. There is no pre-trial disclosure procedure in Austria. The Austrian Code of Civil Procedure provides for a request for the preservation of evidence (Section 384 ZPO), which may be made before the initiation of proceedings, as well as the possibility to demand evidence in possession of the other party during main proceedings (Sections 303 ff, 369 ZPO).

17. However, these options are of limited usefulness in a patent infringement case. This is because – in addition to other procedural hurdles – they cannot be enforced against the will of the defendant and therefore do not play a practical role in patent infringement proceedings.

18. The only option that could be regarded as a very limited form of discovery under specific circumstances under Austrian law is a preliminary injunction for the securing of evidence. Such measures would be enforceable against the will of the defendant and may include evidentiary seizures and searches of the defendant's premises. Like other preliminary injunctions,

a preliminary injunction to secure evidence may be requested before or after main infringement proceedings are initiated.

19. However, to obtain a preliminary injunction for the securing of evidence, the party pursuing the evidence must provide concrete evidence of infringement. Evidence that infringement is merely likely or probable because of economic or technical benefits is insufficient (*Oberlandesgericht Wien,* Higher Regional Court Vienna, 01.04.2020, 133 R 131/19s). Thus, preliminary injunctions for the preservation of evidence are rarely granted because the threshold for obtaining such an injunction is high. Without knowing further details of Sandoz's production process (which Amgen seeks to obtain via the 1782 Application) a preliminary injunction request for the securing of evidence would most likely be denied by an Austrian court.

V. AUSTRIAN COURT'S RECEPTIVITY TO DISCOVERY PURSUANT TO 28 U.S.C. § 1782

20. Documentary evidence obtained through U.S. Section 1782 proceedings may be used in Austrian civil proceedings without limitation.

21. We understand that U.S. District Courts have already addressed Section 1782 applications that pertain to underlying Austrian proceedings and have granted such applications. *In re B&C KB Holding GmbH*, No. 22MC00180LAKVF, 2023 WL 1777326, at *6 (S.D.N.Y. Feb. 6, 2023) (granting request for discovery pursuant to Section 1782 for use in German and Austrian proceedings); *In re Letter of Request from Dist. Ct. of Feldbach, Austria*, No. MC-22-00005-TUC-RM, 2022 WL 657398, at *2 (D. Ariz. Mar. 4, 2022) (granting request for discovery pursuant to Section 1782 for use in Austrian proceeding). In fact, in the *Dist. Ct. of Feldbach* matter, the request for discovery was made directly by an Austrian court. MC-22-00005-TUC-RM, 2022 WL 657398, at *2 ("the foreign tribunal is receptive to, and in fact is requesting, assistance from this Court").

22. The confidentiality of documents submitted during civil proceedings may be ensured in several ways. First, documents may be redacted to maintain confidentiality of information that is not relevant to the case where there is a significant confidentiality interest. In that case, the judge may then request access to the unredacted version of the document (Section 298 ZPO). Second, while hearings in main proceedings are generally public – contrary to hearings in preliminary injunction proceedings – the public may be excluded if confidential information is discussed (Section 172 para 2 ZPO). Lastly, third parties only may access the court files if they have a concrete legal interest in the content of the file, which requires that their legal position is directly affected by the outcome of the proceedings. Other market participants, such as other manufacturers of biosimilars, would not be able to access the file simply because they have a business interest in the case. Even in case of a legal interest, access to the file may be denied to the third party if there are overriding legitimate interests in confidentiality (Section 219 ZPO).

VI. SPECIFIC JUDICIAL ASSISTANCE REQUESTED

23. The Application seeks judicial assistance to obtain documents and testimony for use in the anticipated Austrian Proceeding. The Applicant seeks the requested documents, and related testimony, to support its preliminary injunction motion in Austria.

24. Applicant's requests are narrowly tailored. For example, the discovery requested seeks Sandoz's communications with regulatory bodies about its denosumab biosimilar, and documents that establish the manufacturing processes Sandoz uses and/or intends to use in its manufacture of its denosumab biosimilar. The discovery requested also seeks communications and agreements between Sandoz and Sandoz GmbH (among others) related to the production of Sandoz's denosumab biosimilar. This is all information targeted at confirming that Sandoz's manufacture (or intended manufacture) will infringe at least those European patents (and corresponding Austrian patents) identified above.

Dated: May 9, 2023
Vienna, Austria

Dominik Göbel